

REMARKS

Status of the claims

Claims 99-102 are pending and have been rejected under 35 U.S.C. § 101.

Rejection under 35 U.S.C. § 101

Claims 99-102 are rejected as allegedly supported neither by a specific and substantial utility, nor by a well-established utility. Applicants respectfully traverse the rejection.

Claims 99-102 are directed to nucleic acids consisting of a nucleotide sequence of SEQ ID NO:12 or 13, or nucleic acids encoding a polypeptide consisting of an amino acid sequence of SEQ ID NO 3 or 4. The nucleic acids encode TCP#2, a polypeptide specifically and preferentially expressed in the taste buds of the tongue. These specific nucleic acid sequence are useful as probes, as described in detail below.

In making this rejection, the Examiner alleges that neither the specification as filed nor the art disclose an activity (*i.e.*, biological function) for TCP#2 proteins and concludes that there is no well established utility for the claimed nucleic acids without the disclosure of an biological function for the polypeptide they encode.

As set forth in MPEP §2107, no rejection based on lack of utility should be made if an applicant has asserted a specific and substantial utility that would be considered credible by one of ordinary skill in the art. In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101. (*see*, MPEP §2107.02 III A). The Court of Customs and Patent Appeals stated in *In re Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 183 USPQ 288, 297 (CCPA, 1974, emphasis in original). To overcome the presumption of sufficient utility as asserted by an applicant, the Examiner must

carry the initial burden to make a *prima facie* showing of lack of utility and provide a sufficient evidentiary basis for the conclusion. In other words, the Examiner "must do more than merely question operability--[she] must set forth factual reasons which would lead one skilled in the art to question objective truth of the statement of operability." *In re Gaubert*, 187 USPQ 664, 666 (CCPA 1975).

In the present case, Applicants have clearly described a specific and substantial utility for the claimed nucleic acids that is independent of the biological function of the polypeptides they encode. As set forth in the present specification and explained in the Declaration of Dr. Zuker under 37 C.F.R. §1.132 (filed September 23, 2004), the claimed nucleic acids were identified as taste cell-specific polynucleotides and are useful as specific markers for specialized taste buds of the tongue and for generating taste topographic maps (*see, e.g.*, Declaration, ¶¶ 7-9).

cDNAs that encode a taste cell-specific polypeptides were cloned from a taste cell cDNA library. TCP#2 was identified as a rare sequence preferentially expressed in Gustducin-expressing taste receptor cells of the circumvallate and foliate papillae. (*see, e.g.*, Declaration ¶ 8 and specification at page 8, lines 14-24 and Example 1 at page 54-55). Taste-bud cell specific expression of TCP#2 was confirmed using *in situ* hybridization assays (*see, e.g., id.*)

As attested by Dr. Zuker in his Declaration, it would be apparent to those of skill in the art that TCP#2 is useful as a probe to identify subsets of taste cells (*i.e.*, fungiform cells, foliate cells, and circumvallate cells) and specific types of taste receptor cells (*i.e.*, sweet, sour, salty, and bitter) (*see, e.g.*, Declaration, ¶ 9). TCP#2 can also be used in the generation of taste topographic maps that elucidate the relationship between taste cells of the tongue and taste sensory neurons leading to taste centers in the brain (*see, id.*). Such maps are also useful in pharmacological and food industries for customizing taste, *e.g.*, as probes and markers for taste-induced behaviors (*see, id.*).

Thus, Applicants have asserted a specific and substantial utility in the instant specification and have submitted Dr. Zuker's declaration to demonstrate that this asserted utility is credible to one of skill in the art. In contrast, the Examiner has not provided any evidence or objective reason to overcome the presumed patentable utility. In fact, the notion that one of skill

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in the art would, at the time this application was filed, find the asserted utility credible has been established by Dr. Zuker's declaration and not yet rebutted by the Examiner.


Accordingly, Applicants respectfully submit that the rejection based on alleged lack of utility should be properly withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,


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